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WATER-BASED EXERCISE FOLLOWING STROKE: A RANDOMISED CONTROLLED PILOT STUDY

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Abstract: Background: Decline in mobility is commonly observed following stroke. Reducing the impact of stroke is key to the maintainance of functional independence. Objectives: To determine the acceptability and adherence of a water-based exercise program post-stroke. Design: A single-blind randomised controlled pilot study with masked outcome assessment. Setting: Rehabilitation Unit, Adelaide, South Australia. Participants: 22 community-dwelling older people e living with strokes (6 months-3 years post-stroke). Intervention: Subjects were randomized to either: a six-week water-based intervention group (WG), thriceweekly; a six-week gym-based intervention group (GG), thrice-weekly; or a six-week chronic disease self-management course (CG), once-weekly. Measurements: Assessments took place at baseline, post-intervention and at 3 months follow-up. Primary outcome measures was the 6-minute walk test. Secondary outcomes were measures of balance, body composition, cognition, ADL, goal attainment, quality of life, sleep and fatigue. Results: Recruitment was difficult with only 20% of those approached meeting entry criteria and consenting. A larger increase in walking speed and reduced use of walking aids post-intervention was observed in the WG, however, differences between groups were not significant. No between-group differences were found for any secondary outcomes. The average attendance rate was 90% (n=6). Conclusion: Subjects tolerated the moderate to high intensity water-based exercise program and adherance was good. Although we can not draw firm conclusions due to study completion failure the results suggest that a relatively short program of water-based exercise in stroke survivors is safe and feasible and can improve functional mobility. Hydrotherapy can be delivered with minimal supervision and a well powered trial is needed to assess the effects in chronic stroke patients

Key words: Stroke, water-based exercise, mobility, randomised controlled trial.

Introduction

There are approximately 48.000 stroke events amongst Australians each year. It is the second cause of disease burden in Australia, in terms of 'healthy' life lost due to poor health or disability (1). Loss or limitation of functional movement is a common consequence of stroke. Around 21% will experience a decline in mobility in the first three years which leads to a disruption in usual functioning (2). Reducing the impact of stroke is the key to maintenance of independence and quality of life.

The benefits of water-based exercise have been demonstrated in patients with a range of conditions such as rheumatoid arthritis, osteoarthritis, fibromyalgia and also in the general older adult population (3). Additionally, previous studies have shown high levels of adherence with water-based exercise (4). Water-based

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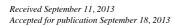
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exercise is possible for patients who are non-ambulatory or have balance issues however there is little evidence supporting water-based exercises after stoke. The objective of this study was to assess the acceptability and adherence of a water-based exercise program in individuals six months to three years post-stroke. Given the susceptibility to deterioration of functional mobility after stroke, successful completion of this study was to inform a future trial. It was anticipated that the water environment would allow patients to exercise at a higher level than would have been possible on land, translating into greater improvements to function.

Methods

Procedure

This was a single blind randomised controlled pilot study with masked outcome assessments. Participants were recruited via the rehabilitation service at the Repatriation General Hospital and key inclusion criteria were: six months to three years since first stroke;





concurrent exercise program.

community dwelling; independent ambulation with or without gait aids; Mini Mental State Exam score of at least 18; ability to accept instruction and able to give consent. Reasons for exclusion were: subsequent stroke; major medical complications following stroke; unstable cardiac conditions; urinary or fecal incontinence; open wounds; tinea; unstable epilepsy or seizures; other comorbid conditions that might contraindicate participation in gym- or water-based exercise; inability to carry out the exercise program; and current participation in a

All eligible participants willing to take part in the study provided written informed consent and were then randomized to receive either: a six-week water-based exercise intervention (3 times/week); a six-week gymbased exercise intervention (3 times/week); or no exercise intervention (waiting list control). Random group allocation was centrally managed by a pharmacist external to the project. Randomisation was generated by a computer software program.

Intervention

The water-based intervention group (WG) received three pool sessions per week for a total of six weeks. Each session was of 40 minutes duration (including aerobic warm up and stretching cool-down) and consisted of a standardised resistance program. Exercises included sideways walking, hip flexion, hip extension, hip adduction, and hip abduction, knee cycling, calf raises, upper body resistance exercises. The intensity of which varied according to each individual's ability, with progressive increase in load over the six week period. Likewise, the gym-based intervention group (GG) received three 40-minute gym sessions (including aerobic warm-up and stretching cool-down) per week for a total of six weeks following a standardised resistance program of which the intensity varied according to each individual's ability, with progressive increase in load over the six week period. Exercises included: bike and arm ergometers, seated bench press, hipflexion, hip extension, hip adduction and hip abduction, triceps pull-down and knee flexion and knee extension. The no-exercise control group (CG) attended a chronic disease self-management course once a week for six weeks. Each session was of 2.5 hours duration and focused on topics such as: symptom management; effective communication with your doctor; and how to lessen frustration, fight fatigue, make daily tasks easier and get more out of life.

Assessments

Assessments took place at baseline, immediately postintervention at 6 weeks and at 3 months follow-up. The primary outcome was gait performance as measured by the six minute walk test (6MTW) (5). Secondary outcome measures were the Modified Berg Balance Scale (MBSS) (6), bioelectrical impedance, Mini Mental Status Examination (MMSE) (7), Modified Barthel Index (MBI) (7), Goal Attainment Scale (GAS)(8), SF-36 (7), Motor Assessment Scale (MAS) (9), MOS Sleep Scale (10), and 10-item Fatigue Assessment Scale (11). Data on demographics (sex, age, etc.), medical history and medications were collected from medical case records or from the subject at baseline. Side effects were monitored but none were reported

Stastictical analysis

Primary analysis for this trial was undertaken using intention to treat principles. Due to the small sample size, non-parametric statistics was used for data analysis. The one-way analysis Kruskall-Wallis test for independent samples was used to determine if there was a statistically significant difference between the groups.

Results

Recruitment commenced in December 2007 and ceased in July 2008. Twenty (16%) of the potential participants could not be contacted (e.g phone cut off or phone not aswered). A total of 106 stroke survivors were approached for the study. Please refer to Table 1 for detailed information on recruitment. A total of 22 (20%) of the patients approached consented and were randomised. Patients characteristics are shown in Table 2. There were 2 withdrawals, 1 in the GG and 1 in the CG. The remaining 20 participants were followed up at the 6week post-intervention assessment. However, the study was terminated prior to the scheduled end date due to funding difficulties and follow-up data at 3 months was collected of 6 patients only. As a result of premature abortion planned sample size could not be achieved and data collection could not be completed.

The exercise intervention was standardized for all subjects, consisting of resistance exercises performed in either the gym or pool. Exercises essentially exerted the same muscle groups in subjects regardless of randomisation to the pool or gym. Variance of intensity (low/medium/high) depended on an individual's ability, however during the intervention period the training load was progressively increased according to the principle of progressive overload (Kraemer).

Study outcomes are presented in Table 3. A larger improvement in gait performance on the 6MTW was evident post-intervention and a reduced use of walking aids was observed in the WG. However, significant differences between groups were not present. A noteworthy improvement in optimal sleep was observed in the WG as measured with the MOS Sleep Scale. The

GAS scores indicated that the WG evaluated themselves best on overall achievement of personal set goals. No significant differences were observed between groups in any of the secondary outcome measures.

Table 1 Recruitment

	number	percentage
Identified actachiel acuticio act	106	
Identified potential participants	126	20.6
not interested	26	20.6
unable to contact / changed phone numbers	20	15.9
satisfied exclusion criteria	20	15.9
self-reported health problems	17	13.5
travelling / transport issues	7	5.6
work commitments / too busy	7	5.6
family member unwell / care responsibilities	6	4.8
unclear reason	6	4.8
going to be away / holidays	5	4.0
water issues	3	2.4
problems with randomization	2	1.6
live to far away	2	1.6
residential / transitional care	2	1.6
scheduled for next trial	1	0.8
not convinced re benefit	1	0.8
past that stage	1	0.8
Included	22	17.5

Adherence was monitored for 6 participants in the WG and the average attendance rate was 90%.

Discussion

We compared water-based therapy to gym-based therapy and no exercise intervention. We demonstrated the feasibility of our protocol in that subjects could tolerate moderate to high intensity exercise programs using a water-based program. Also, the results suggest that a relatively short program of water-based exercise

can improve functional mobility in stroke survivors. Although we cannot draw firm conclusions due to the fact that the study was aborted to completion, studies with small samples add to the body of literature and should contribute to meta-analysis efforts. Accordingly, we hope that the presented data will be used in future meta-analyses which will overcome the limitation of small sample size by pooling study results to generate a single best estimate.

Water-based exercise is considered to be a safe and effective alternative to land-based exercise. Very few studies have been conducted water-based exercises in stroke survivors and only one (12) has measured gait performance. In this study with 12 community-dwelling individuals treatment effects on gait performance were significantly in favour of water-based exercises compared to no-water based exercises (12). Our study results show a trend towards improved walking performance in the WG, however due to the small sample size results did not reach significance and definite conclusions can not be drawn.

Subjects in the WG trained 3 times a week for 40 min and exercised mainly at 50-60% of their baseline agepredicted HR maximum without discomfort. This is consistent with the recommendations by the American Heart Association (13) who prescribes exercise in stroke patients at 50-80% of maximal heart rate, 3-7 days a week with a duration of 20-60 min/day. However, to elicit a training effect increasing the dose may yield better results (14). Studies that have previously shown improvements are based on either 8 or 12-week training programs (15, 16). Adherence was good with a 90% attendance rate in the WG. Due to the physical properties of water, such as buoyancy and hydrostatic pressure, the greater variety of movements, easy-to-do low-impact exercise, pleasant recreational environment and reduced fear of falling may encourage adherence to the training program.

Table 2 Baseline and outcome measures

	Hydro	Gym	Control
Demographics			
Gender (male %)	7 (100)	8 (100)	2 (28.6)
Age (years)	65.7 (8.2) 53-76	73.8 (12.0) 56-88	81.7 (5.8) 70-87
Mini Mental State Examination	27.4 (3.3) 22-30	27.9 (2.9) 20-30	26.1 (3.8) 20-30
Primary outcome measure (change)			
6MTW	35.0 (49.78)	10.9 (33.2)	19.0 (54.6)
Use gait aid (%)	-11.9	3.6	-14.3
Secondary outcome measures (change)			
BMI	0.2 (0.4)	0.3 (0.6)	-0.1 (0.3)
Modified Berg Balance Scale	0.5 (3.0)	0.7 (1.1)	1.4 (1.7)
Modified Barthel Index	1.0 (1.1)	0.57 (1.0)	2.86 (3.4)
EuroQoL	0.46 (0.1)	-0.11 (0.3)	0.11 (0.2)
Motor Assessment Scale	2.4 (2.7)	1.7 (2.1)	3.6 (1.0)
MOS sleep scale	1.6 (12.8)	2.4 (7.7)	9.9 (12.4)
Fatigue Assessment Scale	1.0 (3.7)	0.8 (4.6)	0.0 (5.5)
Goal Attainment Scale	65.7 (4.7)	60.7 (9.7)	57.5 (9.6)



In summary, subjects tolerated the program and the findings of the pilot study are promising considering the relatively short length of the program and incomplete study results. A well powered trial is needed to assess the effectiveness of a water-based exercise program post-stroke. Based on the findings of this pilot study we recommend that a sample size of 152 subjects is required to detect a minimal clinically important difference of 50m (17), based on a two-tailed test at 0.80% power and a significance level of 0.05.

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